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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,324	12/07/2001	Yang-Chang Wu	33144-177127	9479
23639	7590	02/09/2005	EXAMINER	
BINGHAM, MCCUTCHEON LLP THREE EMBARCADERO CENTER 18 FLOOR SAN FRANCISCO, CA 94111-4067			COVINGTON, RAYMOND K	
		ART UNIT	PAPER NUMBER	
		1625		

DATE MAILED: 02/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/005,324	WU, YANG-CHANG
	<b>Examiner</b>	<b>Art Unit</b>
	Raymond Covington	1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  
 THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 09 November 2004.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1,2,5-11,16,17,19,21 and 22 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1,2,5-11,16,17,19,21,22 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
    - a) All    b) Some \* c) None of:
      1. Certified copies of the priority documents have been received.
      2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
      3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____.   |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/9/04</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____.                                   |

Applicants' refer to claim 20 in the response of 11/9/04. However, the listing of claims submitted with the response does not contain a claim 20. Clarification and/or amendment is required.

The rejection of claims 2 and 12-15 under 35 USC 112 2<sup>nd</sup> paragraph has been withdrawn in light of applicants' amendment of 11/9/04.

Claims 6-9 are again rejected under 35 USC 112 1<sup>st</sup> paragraph as failing to comply with the enablement requirement. Applicants' comments have been noted and considered but are not deemed persuasive of patentability. Claim 5 has been withdrawn from this rejection. Claims 6 and 7 are hybrid claims drawn to compositions having cytotoxic activity to human cancer cells. As noted in the previous office action, these claims read on any and all human cancer cells for which there is insufficient enabling disclosure in the specification. Likewise, it is not clear whether this activity is affected in vivo or in vitro. The same would also apply to the hepatoma cancer cells of claim 7 as well as claims 8-9 drawn to methods of treatment.

#### New Rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 6-7 are rejected under 35 USC 112 (first paragraph). The claims are a hybrid of method and compositions. If this is a composition it is recommended that an active ingredient in a therapeutically effective amount and a carrier be explicitly incorporated.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 5-11, 16, 17, 19, 21 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The language of claim 1 is inconsistent and confusing. It is not clear whether claim 1 is drawn to isolating and purifying a mixture of Annonaceous acetogenin compounds “a, b, c...and g” or the claim is isolating and purifying individual Annonaceous acetogenin compounds, “a, b, c... or g”.

Claim 2 under 35 USC 112 second paragraph is rejected as lacking antecedent basis in the claim from which it depends. Claim 2 is drawn to a process of making/isolating compounds “according to claim 1. However, claim 1 is drawn to a mixture of Annonaceous acetogenin compounds and there is no isolating step in claim 2.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The language of claim 5 is inconsistent with claim 1 from which it depends. Claim 5 is drawn to "substantially" pure muricins whereas claim 1 recites isolated and "purified" compounds.

Further, the term "substantially" is a relative term, which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear whether substantially constitutes an effective Amount or some other amount.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond Covington whose telephone number is (571) 272-0681. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, C. Tsang can be reached on (571) 272-0562. The fax

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phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Raymond Covington  
Examiner  
Art Unit 1625

  
RKC

  
Cecilia J. Tsang  
Supervisory Patent Examiner  
Technology Center 1600